



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

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This Document Contains Confidential Information

BARCODE No.: D 440228; **FILE SYMBOL No.:** 91127-RR; **PRODUCT NAME:** E117.01;
DECISION No.: 525430_PC **Code(s):** 097601; **ACTION CODE:** R334; **FOOD Use:** Yes;
COMPANY: Extremis, LLC

DATE OUT. August 11, 2017

SUBJECT: "E11.7.01"

FROM: Indira Gairola / Product Chemistry Team
CITAB / RD (7505P)

TO: Carmen Rodia /Richard Gebken, RM 10
IV Branch 1 / RD (7505P)

The registrant has submitted product chemistry data for the registration of the new end use product "E117.01". In support of the registration application, the registrant is submitting 830 series group A & B product chemistry data with MRID No's. 501322-01 to-04 along with a Basic CSF dated 12/21/16. Applicant claims the subject product to be a "Me Too" of EPA Reg.# 400-154. CITAB has been asked to determine acceptability of the aforementioned data submitted and the proposed CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredients (s): Propargite (69.6%)
2. Has the registrant claimed substantial similarity to a registered product?
[x] Yes; [] No; [] NA; if yes give the registration number of the cited product. EPA Reg.# 400-154
3. All of the source materials of the active ingredient are derived from registered sources- [x] Yes pending registration [] No
4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - [x] Yes; [] No.

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5. Confidential Statement of Formula(s):

☒ Basic— (Dated 12-21-2016)

☐ Re-submitted –

☐ Alternate CSFs

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☒ Yes ☐ NA contains 6 lbs active ingredient per gallon

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☒ Yes; ☐ No; ☐ NA

Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement ☐ Yes ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRI708D Nos. Cited
			Yes	No		
830.1550	Product Identity & Composition		x		A	501322-01
830.1600	Description of materials used to produce the product		x		A	501322-01
830.1650	Description of formulation process		x		A	501322-01
830.1670	Discussion on the formation of impurities		x		A	501322-01
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits				Basic CSF dated 12/21/16
		Proposed Limits	x		A	
		Justification for wider limits				
830.1800	Enforcement analytical method ¹		x		A	501322-02 Validated method was provided

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Clear liquid	A	501322-03
830.6314	Oxidation/ Reduction	Incompatible with 10% KMnO4	A	501322-03
830.6315	Flammability	51°C	A	501322-03
830.6316	Explodability	does not contain any explosive ingredients	NA	
830.7000	pH	4.21 (1% soln. w/w) @ 21.4°C	A	501322-03
830.7100	Viscosity	135.79 centistokes 20°C 33.68 centistokes 40°C	A	501322-03
830.7300	Density (units)	1.048 (g/mL) at 20°C	A	501322-03
830.6317	Storage stability Or Accelerated storage stability	Not submitted	G	
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	Not submitted	G	

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CONCLUSIONS:

NOTE: The registration of the proposed end use product is subject to the approval of the source of active ingredient. (FSN: 91127- pending).

CITAB has reviewed the product chemistry data submitted for the end-use product "E117.01"
and has concluded that:

Substantial similarity to the cited product (**Reg. No. 400-154**)

A.) ☐ Similar

☒ Not similar, give reasons: Density, pH value, Flash Point and the inert components are different

☐ Identical

☐ Not identical

☐ Not applicable

B 1. Basic CSF (dated 05-19-2017)

☒ Acceptable subject to pending registration of the technical used

☐ Not Acceptable

☐ Not Applicable

2.. Alternate CSF ()

☐ Acceptable

☐ Not Acceptable

☒ Not Applicable

If not acceptable give reasons

C. **Group A Product Chemistry Data**

☒ Acceptable

☐ Acceptable with the exception of Guideline (s)

☐ Not acceptable

☐ Not required

☐ Data cited

D. **Group B Product chemistry data**

☐ Acceptable

☐ Not acceptable

☒ Acceptable with the exception of Guideline (s), except guideline (830.6317) Storage stability and (830.6320) Corrosion Characteristic data

☐ Not required

☐ Data cited-not acceptable

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E. Product Label/Draft Label

Recommendations – [x] Yes

1. Since the product was determined to react with oxidizing agents the registrant is recommended to add the following statement on the label under the heading “Physical and Chemical Hazards”
“Do not mix or allow coming in contact with oxidizing agents. Hazardous Chemical Reaction may occur”.

